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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,358	05/17/2002	Maria Davis	PB-9944	9975
22840 7590 08/29/2008 GE HEALTHCARE BIO-SCIENCES CORP. PATENT DEPARTMENT 800 CENTENNIAL AVENUE PISCATAWAY, NJ 08855				
EXAMINER HUTSON, RICHARD G				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
08/29/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/049,358

**Applicant(s)**

DAVIS ET AL.

**Examiner**

Richard G. Hutson

**Art Unit**

1652

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15 and 23-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's response regarding the previous sequence formality issues, in the paper of 6/6/2008, is acknowledged. Applicant's discussion and clarification regarding the discrepancy between current SEQ ID NO: 3 and that originally filed by applicants are appreciated. Claims 15 and 21-28 are still at issue and are present for examination.

Upon further consideration it has been determined that the following rejection is in order and must be resolved prior to the determination of allowable subject matter. This has resulted in the opening up of prosecution and the following non-final office action. Any inconvenience to applicant is regretted.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelfand et al. (US 6,346,379) and Gelfand et al. (US 6,228,628 B1).

Gelfand et al. (US 6,346,379) teach a mutant thermostable Taq polymerase comprising a F667Y mutation and a E681R mutation, wherein said thermostable DNA polymerase has reduced discrimination against incorporation of nucleotides labeled with fluorescein family dyes in comparison to the native form of said enzyme. Gelfand et al. teach that while the specific mutations at position 681 is not as critical as is the position (i.e. position 681) that is mutated. Gelfand et al. also teach methods of synthesizing

fluorescently labeled polynucleotides comprising the use of said mutated Taq DNA polymerase as well as kits comprising said mutant Taq DNA polymerase.

Gelfand et al. (US 6,228,628 B1) teach mutant Taq DNA polymerases comprising a D18A mutation, wherein said mutant DNA polymerase has a reduced 5' nuclease activity and the use of these mutant DNA polymerases in methods of sequencing using fluorescent dye-terminators and kits comprising said Taq polymerase mutants.

One of skill in the art at the time of filing would have been motivated to recombinantly make a mutant Taq DNA polymerase comprising a F667Y mutation and a E681R mutation, as taught by Gelfand et al., and a D18A mutation as taught by Gelfand et al. This mutant Taq DNA polymerase would inherently comprise the amino acid sequence set forth in Figure 3 or SEQ IDNO:3. The motivation for the creation of this triple mutant is that the F667Y mutation and E681R mutations taught by Gelfand et al. (US 6,346,379) are each in the region identified by Gelfand et al. as critical to the incorporation of fluorescein family dyes and the mutation, D18A, taught by Gelfand et al. is in a region critical in the 5'-nuclease activity. Each of the different groups of mutations are shown to result in the same functional change, critical to the incorporation of fluorescein dyes, while they each occur at opposite ends of the polymerase molecule. Thus one of skill in the art would have been motivated to combine these mutants at opposite ends of the polymerase molecule because based on their position in the molecule the effect of the combined mutant would likely be cumulative. The expectation of success is high based upon the results of both Gelfand et al. patents who show that

such mutants can easily be made including double and triple mutants and the creation of such would lead to predictable results. Thus claims 15 and 23-28 are obvious over Gelfand et al. (US 6,346,379) and Gelfand et al. (US 6,228,628 B1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nishaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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8/27/2008

/Richard G Hutson, Ph.D./

Primary Examiner, Art Unit 1652